

REMARKS

Claims 1-3, 5, 6, 10, 11, 14 and 15 have been canceled. Claims 4, 7-9, 12 and 13 remain in the application.

Election of Invention

1.00 *The Examiner held that the application contains claims directed to the following patentably distinct inventions:*

Group I: Claims 1-15, drawn to a composition comprising an organic fluid carrier and a capsaicinoids extract.

Group II: Claim 16, drawn to a method for heightened sensitivity and arousal comprising applying a glycerin carrier and a capsaicinoids extract.

1.20 Applicant's agent has elected to prosecute Group 1, claims 1-15, drawn to a composition comprising an organic fluid carrier and a capsaicinoids extract.

***Objections/Rejections
Under 35 U.S.C. § 103(a)***

2.00 *The Examiner has rejected claims 1 and 2 as obvious over Holt (U.S. 5,869,533, February 9, 1999).*

2.10 The Examiner holds that *Holt* '533 discloses a composition comprising capsaicin (a capsaicinoid) along with carriers such as glycerine and polyethylene glycol (see claims 1-7). *Holt* '533 did not specifically teach wherein the carrier was found in the composition at the specified parts by volume as required by claim 1.

However, *Holt '533* did specifically teach that "Even trace concentrations of capsaicin (such as 0.00001 % by weight) will provide a minute therapeutic effect" and that concentrations greater than 1 % have a burning effect (see col.3, lines 31-34 and claim 2).

One of ordinary skill in the art would have been motivated to prepare a topical composition with the claimed ratio of capsaicin to carrier in order to impart a warming effect without burning. It is clear from *Holt '533* that concentrations as low as 0.00001 % have therapeutic value.

2.20 Applicant has canceled claims 1 and 2 and thus, the rejection of claims 1 and 2 over the *Holt '533* reference need not be addressed.

***Objections/Rejections
Under 35 U.S.C. § 103(a)***

3.00 The Examiner has rejected claims 1 and 2 as obvious over *Lezday et al.* (U.S. 6,428,791, August 6, 2002).

3.10 The Examiner holds that *Lezday et al. '791* discloses a taught a topical lubricating composition for enhancing sexual performance comprising capsaicinoids, primrose oil and carriers such as propylene glycol (see Example 4 and claims 1-4).

Lezday et al. '791 did not specifically teach the ratio of an organic fluid carrier to the capsaicin. Although *Lezday et al. '791* did not specifically teach the ratio of an organic fluid carrier to the capsaicin, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations of capsaicin because concentration is an art-recognized result-

effective variable which would have been routinely determined and optimized in the pharmaceutical art. One of ordinary skill in the art would have been motivated to adjust the concentration of capsaicin in order to moderate/vary the degree of heat associated with the product: i.e., mildly hot -vs- extra hot.

3.20 Applicant has canceled claims 1 and 2 and thus, the rejection of claims 1 and 2 over the *Lezday et al.* '791 reference need not be addressed.

Objections/Rejections
Under 35 U.S.C. § 103(a)

4.00 *The Examiner has rejected claims 4, 5, 8 and 10 as obvious over Lezday et al. '791 and further in view of Nicolicchia (U.S. 5,770,206, June 23, 1998).*

4.10 The Examiner holds that *Lezday et al. '791* did not disclose wherein honey or a colorant was added into the composition.

Nicolicchia '206 taught a body oil for use as a 'sexual stimulant' which comprised paprika for color and honey for taste (see col. 2, lines 10-16).

One of ordinary skill in the art would have been motivated to add honey to the composition disclosed by *Lezday et al. '791* in order to impart a palatable taste to the composition. Further, one of ordinary skill in the art would have been motivated to add a colorant to the composition disclosed by *Lezday et al. '791* in order to impart color to the composition. The addition of these materials were common in the practice of making sexual lubricants/body oils and would make the product more attractive to consumers.

4.20 Applicant has amended claim 4 to include the limitations of claims 7, 10 and 11. Claim 4, as amended, includes the following limitations:

A topical composition for heightened sensitivity and arousal in humans comprising;

- (a) an organic fluid carrier present at about 98,578 parts to about 157,725 parts by volume;
- (b) capsaicinoids extract present at about 1 part by volume;
- (c) honey present at about 1540 parts to about 2463 parts by volume;

- (d) evening primrose oil present at about 256 parts to about 410 parts by volume;
- (e) a coloring material to impart a color to the topical composition; and
- (f) vanilla extract to impart an odor to the topical composition.

Applicant holds that the volumetric relationships between the organic fluid carrier, the capsaicinoids extract, the honey and the evening primrose oil serve to distinguish the composition of the present invention of claim 4, as amended, over the cited references. It is imperative to limit the upper volumetric concentration of the capsaicinoids extract in the present composition in order to prevent discomfort when applied to the genital area of the user. The additional limitation of the presence of vanilla extract to impart an odor to the present composition further serves to distinguish the composition of claim 4 over the *Lezday et al.* '791 and *Nicolicchia* '206 references.

Applicant respectfully requests that the Examiner withdraw the rejection of claim 4, as amended, under 35 U.S.C. 103 (a), in view of the amendments to claim 4.

Applicant holds that since claim 4 is patentable, dependent claims 8 and 9 are also now patentable in that these claims now recite more specific embodiments of the present invention. Applicant respectfully requests that the Examiner withdraw the rejection of claims 8 and 9 under 35 U.S.C. 103 (a), in view of the amendment to claim 4.

Objections/Rejections
Under 35 U.S.C. § 103(a)

5.00 *The Examiner has rejected claims 6, 9, 12 and 13 as obvious over Lezday et al. '791 in view of Nicolicchia '206 and further in view of Voss et al. (U.S. 4,801,587, January 31, 1989).*

5.10 The Examiner holds that neither *Lezday et al.* '791 nor *Nicolicchia* '206 specifically taught wherein their compositions contained glycerin as the carrier.

Voss et al. '587 taught that glycerin was a conventionally used carrier in topically applied compositions for treatment of impotence (see col. 3, lines 42-50).

One of ordinary skill in the art would have been motivated to substitute the propylene glycol

disclosed by *Lezday et al.* '791 with glycerin, as glycerin would have acted as a functional equivalent to propylene glycol in lubricating capacity especially lacking any evidence to the contrary, and lacking any unexpected results.

Although none of the references taught the concentrations of ingredients as found in claim 12, again, concentration is a result-effective variable; wherein finding optimal ranges is considered routine in the art of pharmacology.

5.20 Applicant has amended claim 12 to include the limitations of claims 14 and 15. Claim 12, as amended, includes the following limitations:

A topical composition for heightened sensitivity comprising;

(a) about 98,578 parts to about 157,725 parts by volume of glycerin;

(b) about one part by volume of capsaicinoids extract;

(c) about 1540 parts to about 2463 parts by volume of honey; and

(d) about 256 parts to about 410 parts by volume of evening primrose oil;

(e) a coloring material to impart a color to the topical composition; and

(f) vanilla extract to impart an odor to the topical composition.

Applicant holds that the volumetric relationships between the specific fluid carrier glycerin, the capsaicinoids extract, the honey and the evening primrose oil serve to distinguish the composition of the present invention of claim 12, as amended, over the cited references. It is imperative to limit the upper volumetric concentration of the capsaicinoids extract in the present composition in order to prevent discomfort when applied to the genital area of the user. The additional limitation of the presence of coloring material in impart a color to the present composition, and vanilla extract to impart

an odor to the present composition further serves to distinguish the composition of claim 12 over the *Lezday et al.* '791, *Nicolicchia* '206 and *Voss et al.* '587 references.

Applicant respectfully requests that the Examiner withdraw the rejection of claim 12, as amended, under 35 U.S.C. 103 (a), in view of the amendments to claim 12.

Applicant holds that since claim 12 is patentable, dependent claim 13 is also now patentable in that this claim now recites a more specific embodiments of the present invention. Applicant respectfully requests that the Examiner withdraw the rejection of claim 13 under 35 U.S.C. 103 (a), in view of the amendment to claim 12.

Objections/Rejections
Under 35 U.S.C. § 103(a)

6.00 *The Examiner has rejected claims 11 and 15 as obvious over Lezday et al. '791 in view of Nicolicchia '206 in view of Voss et al. '587 and further in view of Geria et al. (U.S. 4,780,309, October 25, 1988).*

6.10 The Examiner holds that none of these references specifically suggested the incorporation of a vanilla extract in order to impart an odor to the composition.

Geria et al. '309 disclosed a palatable aerosol oil containing foam comprising vanillin (an extract of vanilla) (see Example 1).

One of ordinary skill in the art would have been motivated to add vanillin to the composition in order to impart a favorable odor thereby rendering the composition more attractive to the consumer.

It is clear from the prior art references that the addition of carriers/colorants/flavorants were routine in the art. It would not have required a substantial inventive contribution in order to impart known, conventional carriers, colorants and flavorants to the composition, as addition of these additives were, again, typically added to topical formulations.

From the teachings of the references, it is apparent that one of ordinary skill in the art would

have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6.20 Applicant has canceled claims 11 and 15 and thus, the rejection of claims 11 and 15 over the *Lezday et al.* '791, *Nicolicchia* '206, *Voss et al.* '587 and *Geria et al.* '309 references need not be addressed.

CONCLUSION

Applicant respectfully traverses the Examiner's rejection and requests reconsideration. Applicants respectfully submit that the pending claims 4, 7-9, 12 and 13, as amended, are in condition for allowance and be passed to issue.

Respectfully submitted,

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